

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE ACTOS ANTITRUST LITIGATION	
THIS DOCUMENT RELATES TO:	Master File No. 1:13-cv-09244-RA-SDA
ALL ACTIONS	

**REPLY IN SUPPORT OF PLAINTIFFS' LETTER MOTION REGARDING
DOCUMENTS SUBJECT TO TAKEDA'S PRIVILEGE WAIVER**

INTRODUCTION

Takeda’s assertion that that it can limit its privilege waiver to some “specific,” “narrow” subject matter (ECF No. 403 (“Opp.”) at 1, 2, 8)—while also asserting a regulatory compliance defense—is simply incorrect. The law is clear: the scope of Takeda’s waiver is determined by the elements of its affirmative defense.¹ That defense requires Takeda to prove that when it engaged in the challenged conduct—*i.e.*, the submission of false patent information to the FDA for listing in the Orange Book, and the maintenance of those listings from 1999 to 2012—Takeda acted “reasonably” and “in good faith to comply with a regulatory mandate.”² The defense thus puts at issue the reasons why Takeda made and maintained the wrongful patent submissions. Under Second Circuit case law, Plaintiffs are entitled to all documents relevant to this defense so that they can test its validity. If Takeda wishes to waive privilege only as to some narrower category of documents, it must forgo the defense.³

While insisting on the “narrowness” of its waiver, Takeda nevertheless claims to “already [be] producing ‘all evidence’ . . . relevant to its good faith compliance defense.” (Opp. at 10.) This is wholly inaccurate. Takeda’s view of the waiver excludes a host of documents relevant to its defense, including, most critically, documents concerning Takeda’s *actual motives* for engaging in the challenged conduct. (Opp. at 2.) Takeda’s reasons for engaging in the alleged misconduct are highly probative of its defense. As the case law makes clear, evidence that a defendant acted with

¹ As discussed further below, Takeda wildly mischaracterizes the elements of this defense in its brief. *See infra* at §A.

² *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 372 (S.D.N.Y. 2019); *id.* at 375 (Takeda, as the party asserting the affirmative defense, has “the burden of demonstrating a good faith effort to comply with mandatory regulations.”).

³ *See, e.g., Arista Records LLC v. Lime Grp. LLC*, No. 06-5936, 2011 U.S. Dist. LEXIS 42881, at *5 (S.D.N.Y. Apr. 14, 2011) (precluding defendants from offering evidence of purported good faith belief in the lawfulness of their conduct because defendants repeatedly invoked privilege to block the plaintiff’s discovery of facts that may have served as the basis for alleged good faith belief).

anticompetitive intent is inconsistent with a claim of good faith regulatory compliance.⁴ Plaintiffs are thus entitled to understand all of Takeda's reasons for engaging in the challenged misconduct so that they may determine whether Takeda's purported "good faith" justifications are valid, or whether they are instead efforts to "rationalize a decision whose purpose is anticompetitive."⁵

Takeda also attempts to limit the scope of its waiver in other arbitrary and improper ways. For example, it states repeatedly that its waiver only concerns "pre-2003 regulations" and excludes all documents regarding "post-2003" regulations, upon which Plaintiffs' claims are purportedly "based." (Opp at 1, 2, 7.) The distinction Takeda attempts to draw between some unspecified pre- and post-2003 regulations is nonsensical. Plaintiffs' claims are overwhelmingly based on Takeda's violation of statutory and regulatory listing obligations that were in effect at the time of the 1999 and 2002 listings, and which remained constant from 1999 to 2012. Takeda cannot arbitrarily limit its waiver by reference to a strawman. Takeda also seems to improperly limit its waiver temporally. It lists four "contexts" in which it believes documents subject to the waiver "arise," all of which are from 2009 and 2010. (Opp. at 8.) Takeda does not include its original listings of the patents as one such "context." Takeda cannot exclude from its waiver documents from key time periods if it wishes to assert good faith regulatory compliance as a complete defense to liability.

Takeda's actions during just the course of this briefing confirm that it has not conducted a coherent privilege review, and, as a result, has improperly withheld many communications subject to the waiver. After receiving the list of documents Plaintiffs selected for *in camera* review, Takeda informed Plaintiffs that one had been improperly withheld and fell within the scope of its

⁴ *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d at 371 (quoting *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d 980, 1009 (1984) (whether a defendant was motivated by "competitive considerations" is relevant to regulatory compliance defense).

⁵ *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d 980, 1009 (1984).

waiver. Takeda then asked Plaintiffs to identify a replacement document to provide to the Court.⁶ Plaintiffs declined to replace the document, as it would defeat the purpose of *in camera* review to allow Takeda to eliminate from the Court's ambit documents calling into question the propriety of Takeda's categorical withholdings. Two days later, Takeda announced that it would seek to claw back two documents cited in Plaintiffs' letter motion concerning its settlement strategy. These documents—which had been redacted after review by Takeda prior to production, and which had been brought to Takeda's attention in prior correspondence—are plainly not the product of inadvertent disclosure. Instead, they are a last-ditch, failed effort by Takeda to blunt Plaintiffs' contention that Takeda has selectively produced some documents and withheld others.

In light of Takeda's improperly narrow interpretation of its waiver and the many glaring, ongoing issues with its privilege withholdings,⁷ Plaintiffs reiterate their request for an order (1) clarifying that the scope of Takeda's waiver includes all documents relevant to its affirmative defense, and (2) compelling Takeda to produce the documents described in Plaintiffs' Motion and Proposed Order, (ECF No. 395), by September 23, 2022.

BACKGROUND

The categories of withheld and redacted documents at issue concern Takeda's motivations with respect to specific anticompetitive acts Takeda is alleged to have engaged in between 1999 and 2012, which violated statutory and regulatory mandates concerning the

⁶ Takeda also informed Plaintiffs that it needed this replacement by 3pm on Labor Day so that Takeda could translate the document for the first time.

⁷ While Takeda mentions that it has now begun to produce documents from Hogan Lovells, (Opp. at 7, n.7), it omits to mention that it agreed to do so only after Plaintiffs issued a non-party subpoena on the law firm and that it is withholding and redacting documents from the Hogan Lovells file. Prior to that subpoena, Takeda withheld those documents on the basis that Hogan Lovells was not an agreed-upon "data source." Takeda has also yet to substantially produce documents from its in-house counsel, George Kokkinnes and Mark Buonaiuto, who were two of the primary architects of Takeda's wrongful listing scheme, and whose documents are plainly subject to the waiver. Takeda also continues to produce new and inscrutable categorical privilege logs, which do not provide Plaintiffs with nearly enough information to assess Takeda's claims of privilege with respect to individual withheld documents.

submission of patent information to the FDA. Plaintiffs allege that these acts were designed to, and did, unlawfully extend Takeda's monopoly over the drug Actos.

Plaintiffs' allegations arise out of Takeda's scheme to unlawfully extend its monopoly over its blockbuster drug Actos (pioglitazone hydrochloride). Specifically, Plaintiffs allege that Takeda submitted false and misleading patent information regarding two patents to the FDA for publication in the Orange Book. (DPP Compl.⁸ ¶¶8; EPP Compl.⁹ ¶4.) In 1999 and 2002, Takeda asserted in its patent submissions to the FDA that U.S. Patent Nos. 5,965,584 ("the '584 Patent") and 6,329,404 ("the '404 Patent") claimed the drug product Actos when, in fact, both patents plainly and unambiguously do not, a fact confirmed by contemporaneous documents. (DPP Compl. ¶¶8; EPP Compl. ¶4.) The '584 Patent *only* claims a method of using pioglitazone hydrochloride with metformin (biguanide), and a drug product consisting of pioglitazone hydrochloride and a biguanide. (DPP Compl. ¶¶8; EPP Compl. ¶65.) The '404 Patent claims a method of using pioglitazone hydrochloride with insulin, and a drug product consisting of pioglitazone hydrochloride and an insulin secretion enhancer. (DPP Compl. ¶¶8; EPP Compl. ¶66.) While each patent might claim a particular *method of using* Actos, neither claims the drug product Actos itself. (DPP Compl. ¶¶8; EPP Compl. ¶¶65-66.) The Second Circuit confirmed Plaintiffs' allegations that Takeda's patent listings were improper: "under the 'Listing Requirement' of 21 U.S.C. § 355(b)(1), the '584 and '404 Patents do not 'claim the drug' ACTOS."¹⁰

Takeda's false and misleading patent descriptions to the FDA had dramatic regulatory consequences and stymied generic competition. Because Takeda falsely described the patents as

⁸ Fourth Consol. Class Action Compl. & Jury Demand, 15-cv-03278, ECF No. 152 (Nov. 20, 2019) ("DPP Compl.").

⁹ Fourth Consol. Class Action Compl. & Jury Demand, ECF No. 255 (Mar. 14, 2018) ("EPP Compl.").

¹⁰ *United Food and Comm. Workers Local 1776 & Participating Employers Health and Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 136 (2d Cir. 2021).

claiming the Actos drug product, a generic seeking to enter the market before the patent expires must file a “paragraph IV” certification stating that its generic product does not infringe any valid, enforceable patent. (DPP Compl. ¶¶9; EPP Compl. ¶¶45.) Such certification constitutes an artificial act of infringement, enabling the patent holder to sue the generic; the ensuing litigation automatically stays the FDA’s approval of the generic’s Abbreviated New Drug Application (“ANDA”) for two and a half years; and additional generic approvals are further bottlenecked behind the first generic filer’s 180-day exclusivity. (DPP Compl. ¶¶9; EPP Compl. ¶¶45.) Had Takeda properly described the patents as claiming only methods of using Actos, the generics could have “carved out” those patented uses from their labels by filing a “section viii statement” and avoided the Paragraph IV entry barriers. (DPP Compl. ¶¶9; EPP Compl. ¶¶46.)

Takeda’s submission of false and misleading patent information regarding the ’584 Patent and ’404 Patent for Actos forced the FDA not to accept section viii statements from prospective generic Actos competitors. (DPP Compl. ¶¶11; EPP Compl. ¶¶74.) Takeda’s wrongful listings also led the first generic manufacturer that filed an ANDA with a paragraph IV certification to procure the 180-day exclusivity provided by the Hatch-Waxman Act. (*Id.*) That 180-day exclusivity is not available if only section viii statements are made. (*Id.*) Here, the exclusivity prevented the FDA from approving any other ANDAs for generic Actos products until 180 days after the first filers entered. (*Id.*)

Generic competition for Actos was likely to begin immediately after Actos’s drug substance patent, U.S. Patent No. 4,687,777 (the “777 Patent”), expired on January 17, 2011. (DPP Compl. ¶¶15; EPP Compl. ¶¶6.) Takeda sued manufacturers that sought the FDA approval to sell generic Actos, even though they had carved out the patented methods of using their generic Actos products. (*See, e.g.*, DPP Compl. ¶¶15; EPP Compl. ¶¶¶90, 95, 106.)

In the course of ongoing settlement negotiations in 2009, the generic company Sandoz submitted a Citizen Petition concerning Takeda's patent listings, seeking a ruling from the FDA requiring all prospective generics manufacturers to address the '404 and '584 patents with Paragraph IV certifications. (DPP Compl. ¶¶254; EPP Compl. ¶¶72.) The FDA granted that petition in 2010, based on Takeda's wrongful patent submissions in 1999 and 2002, which Takeda confirmed to the FDA via correspondence in 2009 and public comment in 2010. (DPP Compl. ¶¶256; EPP Compl. ¶¶71-73.) In 2010, Teva challenged the accuracy of the listings under 21 CFR 314.53(f), triggering the FDA to request that Takeda confirm or correct its listing information. In response, Takeda again represented that its patent descriptions were correct. Teva also sought leave to file a counterclaim directly challenging Takeda's patent listings as improper. (DPP Compl. ¶¶303-313; EPP Compl. ¶¶103.) But as the Second Circuit held, by that point, "the damage had been done."¹¹

With the first-filers' right to 180-day exclusivity thus guaranteed, they agreed to delay entry into the market until August 17, 2012. The later filers were stuck behind the first filers' 180-day exclusivity, and most of their 30-month stays would extend into 2012 or beyond, so they agreed to delay entry of their ANDA products until February 2013. (DPP Compl. ¶¶270-273; EPP Compl. ¶¶86, 91, 96.)

ARGUMENT

A. Takeda Grossly Mischaracterizes the Elements of the Regulatory Compliance Defense.

Takeda does not take issue with the fundamental proposition that the scope of its privilege waiver is determined by a document's relevance to Takeda's good faith compliance defense; instead, Takeda merely purports to have a different view about which documents are relevant.

¹¹ *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 100 (2d Cir. 2017).

Such relevance assessment must begin with a proper understanding of the defense. The regulatory compliance defense is a “defense to antitrust liability where the defendant’s action was taken as part of a good faith, reasonable attempt to comply with a regulatory scheme.”¹² As such, the defense entails an objective element (reasonableness) and a subjective one (good faith).¹³ It is applicable only if the defendant’s “basis” for its decision to undertake the challenged conduct was “reasonable” and the defendant made its decision on that basis—and not other, improper bases—in good faith.¹⁴ Accordingly, evidence as to whether the challenged acts were done “on the basis of competitive considerations” is highly relevant to the defense.¹⁵

In its Opposition, Takeda disregards case law establishing the elements of the regulatory compliance defense in antitrust cases, and instead invents a new standard out of whole cloth. Takeda’s opposition largely ignores the “reasonableness” prong. As to the “good faith” prong of the defense, Takeda describes it as “test[ing] whether ‘a defendant knew that an objectively reasonable statutory meaning was improper and yet still heeded it.’” (Opp. at 12.) This framing is a complete fabrication and appears to be manufactured by Takeda to fit its needs in this litigation. Indeed, Takeda’s sole support for this novel understanding of “good faith” is cribbed from a footnote in the Second Circuit’s decision in this case addressing an entirely separate issue.¹⁶ The Second Circuit footnote says in its entirety:

Takeda’s reasoning also requires an additional, unspoken inferential step—that as long as the proffered interpretation is objectively reasonable, even a purposeful misinterpretation of the statute cannot be willfully improper. Because we conclude that objective reasonableness in the first place does not preclude Plaintiffs-Appellees’ monopolization claim, ***we need not address*** a scenario in which a

¹² *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 12 (1st Cir. 2020).

¹³ *See, e.g., id.* at 13 (discussing elements of the regulatory compliance defense).

¹⁴ *See In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d at 371 (quoting *S. Pac. Commc’ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d 980, 1009 (1984)).

¹⁵ *S. Pac. Commc’ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d at 1009.

¹⁶ *United Food & Commer. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th at 137-38 (holding that Plaintiffs were not required to aver that Takeda’s listing decisions were “unreasonable” to adequately allege monopolization).

defendant knew that an objectively reasonable statutory meaning was improper and yet still heeded it.¹⁷

Nowhere in that footnote (nor elsewhere in the opinion) does the Second Circuit address or define the elements of the regulatory compliance defense. As the cases cited in Plaintiffs' opening brief make clear, this defense puts at issue the defendant's "state of mind" with respect to its misconduct, resulting in an implied waiver as to all evidence thereof.¹⁸ Despite its request for extra pages to brief its opposition, Takeda fails to address the binding Second Circuit case-law Plaintiffs' cite in their opening brief, which explains the correct standard.

Takeda's gross mischaracterization of the regulatory compliance defense is beyond the pale and should be rejected by the Court. Takeda cannot (and does not) coherently identify which documents are relevant to its regulatory compliance defense, and therefore subject to the waiver, because it does not even clearly or consistently articulate the basic elements of the defense.

B. Evidence of Takeda's Motives Falls within the Scope of the Waiver.

Takeda contends, based on its mischaracterization of the regulatory compliance defense, that evidence of Takeda's state of mind with respect to the challenged conduct (including its motives) is not relevant to its defense. (Opp. at 12.) According to Takeda, "the only question" its good faith defense "addresses" is whether "Takeda believed that the pre-2003 regulations did not apply or that, even if applicable, Takeda believed that its conduct did not comply with these regulations but nevertheless still engaged in the conduct." (Opp. at 2-3, 12-13.) This tortured sentiment—which Takeda recites twice in its brief—has no basis in law.

The Second Circuit is clear that by asserting a defense of good faith, Takeda put at issue its "state of mind, which typically calls forth the possibility of implied waiver of the attorney-

¹⁷ *Id.* (emphasis added).

¹⁸ ECF No. 394 at 3 (citing *United States v. Bilzerian*, 926 F.2d 1285, 1292-94 (2d Cir. 1991)).

client privilege.”¹⁹ Plaintiffs’ efforts to procure state-of-mind documents, including documents showing Takeda’s *reasons* for engaging in the challenged conduct, is not a “fishing expedition” (Opp. at 14), but a matter of fairness and black letter law.²⁰ One of the main purposes of discovery is to enable the parties to test the asserted claims and defenses. If Takeda is going to assert that its true motivation to engage in the challenged conduct was the “advice of highly-experienced and qualified outside counsel” (Opp. at 10–11), Plaintiffs should, in fairness, be allowed to test that theory with documents showing any and all other motives. Takeda claims that “[i]f the Plaintiffs wish to probe further into whether Takeda acted with anticompetitive intent, they may do so with non-privileged information.”²¹ This misses the point. The existence of relevant, non-privileged documents does not negate the fact that the privileged documents are required to test Takeda’s defense. Takeda could have sought to prove its defense using only non-privileged information. It chose not to do so. Instead, Takeda has put into question what the reasons were that its attorneys advised it to take the actions being challenged in this case. It must produce all privileged and non-privileged documents relevant to that question.

Documents showing that Takeda might have acted with anticompetitive intent are particularly probative of Takeda’s claims of an alleged “good faith” basis for its misconduct. As courts have made clear, such evidence undermines—and, in some cases, can outright defeat—an antitrust defendant’s “good faith” defense.²² Plaintiffs are entitled to understand *all* of Takeda’s reasons for engaging in the challenged conduct so that they may determine whether Takeda’s

¹⁹ *Pritchard v. Cty. of Erie (In re Cty. of Erie)*, 546 F.3d 222, 228–29 (2d Cir. 2008); *Newmarkets Partners, LLC v. Sal. Oppenheim Jr. & Cie. S.C.A.*, 258 F.R.D. 95, 111 (S.D.N.Y. 2009) (“selective disclosure of any privileged documents supports the conclusion” a party has “forfeited their privileges with respect to other communications on the same subject”).

²⁰ *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) (“privilege may implicitly be waived when defendant asserts a claim that in fairness requires examination of protected communications.”)

²¹ Opp. at 13–14.

²² *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d at 371 (quoting *S. Pac. Commc’ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d 980, 1009 (1984).

supposed justifications are mere efforts to “rationalize a decision whose purpose is anticompetitive.”²³

C. Takeda’s Framing of a “Narrow” Express Waiver is Arbitrary and Excludes Documents Relevant to Takeda’s Affirmative Defense.

Despite claiming to “already” be producing all documents relevant to its affirmative defense (Opp. at 10), Takeda’s “narrow” view of the waiver excludes numerous categories of relevant documents. For example, Takeda states that its waiver applies only to “pre-2003 regulations,” and to not to so-called “post-2003 regulations,” upon which Plaintiffs claims are purportedly “based.”²⁴ (Opp. at 1.) The supposed distinction between “pre-” and “post-2003 regulations” is nonsensical. The statutory and regulatory provisions Plaintiffs allege Takeda violated with its false listing scheme—including the listing obligations set forth in 21 U.S.C. § 355(b) and 31 CFR § 314.53—were in effect prior to 2003 and remained in effect thereafter. The Second Circuit ruled that Takeda’s patent descriptions were improper under the then-applicable statute and regulatory policies.²⁵ Takeda’s repeated assertion that it has waived privilege only as to “pre-2003” regulations is therefore meaningless. But it serves as a smokescreen that enables Takeda to selectively waive privilege, improperly using privilege as both a “sword” and “shield.”

Takeda also seems to limit its waiver temporally, noting four “contexts” in which documents subject to the waiver “arise,” all of which are from 2009 and 2010. (Opp. at 8.) Takeda

²³ *S. Pac. Commc’ns Co. v. Am. Tel. & Tel. Co.*, 238 U.S. App. D.C. 309, 740 F.2d at 1009.

²⁴ The suggestion that Plaintiffs’ claims are premised only on “post-2003 regulations” is ludicrous. Plaintiffs allege that Takeda’s false and misleading patent descriptions ran afoul of statutes, regulations, and the FDA guidance going back as far as 1994. (*See* DPP Compl. at ¶¶ 74–76 (describing § 505(b)(1) of FDCA—which requires NDA applicants to submit the number of any patents claiming the drug for which the applicant submits an application, or any method of using such drug—and noting that this statutory requirement was unchanged during all periods relevant to this litigation); ¶¶ 78–80 (describing 21 CFR § 314.53, an FDA rule issued October 3, 1994, that imposed obligations on NDA applications regarding the submission of patent information and created ongoing reporting requirements); EPP Compl. ¶ 44 (same).)

²⁵ *United Food & Commer. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 136 (2d Cir. 2021)

does not include the original listing of its patents in 1999 and 2002 as such “contexts,” even though Takeda’s initial improper submissions are central to Plaintiffs’ liability theory. To be clear, Takeda’s statement that “[t]he only alleged conduct forming the basis for Plaintiffs’ claims is Takeda’s decision in November 2009 and January 2010 to maintain its patent descriptions” is incorrect. Opp. at 6. The challenged conduct includes Takeda’s 1999 and 2002 listings, and the maintenance thereof.²⁶ If Takeda wishes to assert good faith regulatory compliance as a complete defense to liability, it cannot exclude from its waiver documents from the period before 2009.

D. Takeda’s Waiver Determinations are Incoherent, Inconsistent, and Demonstrate Last-Minute Gamesmanship.

Takeda’s actions during the course of this briefing confirm that it has not conducted a thorough or coherent privilege review and has withheld many communications subject to the waiver. On September 2, 2022, pursuant to this Court’s express order, Plaintiffs provided Takeda with a list of 18 withheld or redacted documents they selected for *in camera* review. Plaintiffs were forced to make these selections largely in the dark. Because Takeda has not provided individual descriptions for each of its withheld or redacted documents, Plaintiffs had to guess at their contents by reference to incomplete metadata, such as dates, recipient lists, and email subjects. Following receipt of Plaintiffs’ list, Takeda confirmed that at least one of the documents identified [REDACTED]

²⁶ Takeda cites the Second Circuit’s 2017 opinion for the notion that the “initial submission of patent information . . . did not cause the alleged harm.” (Opp. 6 n.6.). This is not true. The 2009 and 2010 actions by Takeda arose from those 1999 and 2002 listings, which the Second Circuit in 2017 recognized. *In re Actos End-Payor Antitrust Litigation*, 848 F.3d 89, 100 (2d Cir. 2017) (accepting Plaintiffs’ causation theory “because ‘Takeda’s *original* patent declaration to FDA for the ’584 and ’404 patents stated that the patents included drug product claims and method-of-use claims’”) (emphasis added). The Second Circuit then held in 2021 that those initial submissions were unlawful. 11 F.4th at 124 (“Those representations”—made “[o]n November 5, 1999, and January 3, 2002”—“triggered a series of procedural safeguards under the Hatch–Waxman Act. . .”). In addition, the Second Circuit’s 2017 opinion held that the initial submissions did not cause the paragraph IV certifications made before the FDA’s ruling on Sandoz’s citizen petition. But the Second Circuit held that initial submissions did cause the paragraph IV certifications by Teva, which, before the FDA’s ruling on the Sandoz citizen petition, was relying exclusively on section viii to enter the market. Plaintiffs amended their complaints to show that, in addition to Teva, many other generics had filed paragraph IV certifications only after the FDA’s decision on Sandoz’s citizen petition.

[REDACTED] (TAK-ACTOS_000524308) — was subject to the waiver under even Takeda’s narrow view, and had been wrongly withheld. Takeda requested Plaintiffs withdraw their request to submit this document to the Court, and instead select a replacement document to provide the Court. Plaintiffs declined, noting that the purpose of *in camera* review of a sample of documents is to determine whether there are global issues with Takeda’s privilege withholdings.

Then, on September 6, the day its opposition brief was due, Takeda announced that it intended to claw back two documents that Plaintiffs cited in their motion to compel (TAK-ACTOS_000527117 and TAK-ACTOS_000527129) regarding Takeda’s settlement strategy in the underlying patent litigations. These documents—which had been carefully reviewed and redacted by Takeda prior to their production, and which had been the subject of Plaintiffs’ prior correspondence (Ex. A)—are plainly not the product of any inadvertent disclosure. Takeda seeks to claw back these documents now for the purpose of this briefing, presumably to counter Plaintiffs’ argument that Takeda has selectively produced only some documents concerning its settlement strategy.

Takeda’s selective production strategy extends to the Hogan Lovells documents that Takeda touts in its opposition. (Opp. 7 & n.7.) What Takeda fails to mention is that it is withholding a substantial number of Hogan Lovells documents from the representation at issue. In 2009, Takeda retained Hogan Lovells (and its attorneys [REDACTED]) to advise on the regulatory question at issue in Takeda’s defense: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] All documents related to this retention should have been

produced even under Takeda's view of the scope of the waiver because they are directly relevant to the advice Takeda claims is within the scope, and they are relevant to the reasons for and reasonableness of Takeda maintaining its wrongful listings. Yet in Takeda's first rolling production of these documents, it withheld dozens as privileged. While Plaintiffs do not have full visibility into the documents that have been withheld, Takeda has disclosed that they include the billing records and retention agreements for this representation.

E. Documents Concerning Takeda's Settlement Strategy in the Underlying Litigation are Highly Relevant to its Regulatory Compliance Defense and Must be Produced in full.

One particularly glaring example of Takeda's improper holdings—and the only category of documents Takeda addresses directly in its opposition—is documents from the underlying patent litigation, and in particular settlement-related documents. Notwithstanding the last-minute claw back discussed above, Takeda continues to selectively produce documents related to its patent litigation settlement strategy. These include [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Such production demonstrates Takeda's recognition that patent litigation documents—especially the settlement-related documents—do fall within the scope of its waiver, and should be produced.

These documents suggest that the reason Takeda affirmed its wrongful listings in 2009 and 2010 was to eliminate the threat of a Teva section viii entry on January 17, 2011, which stood

in the way of Takeda's efforts to perfect anticompetitive settlements that bound all generics to delayed entry dates. Given their relevance to Takeda's state of mind with respect to the alleged misconduct—and to the specific question of whether Takeda's 2009 and 2010 reaffirmations of its wrongful listings were actually made in "good faith" based on a reasonably understood regulatory mandate, or instead were undertaken with anticompetitive intent—Plaintiffs are entitled to all documents regarding Takeda's settlement strategy, not just the handful it has chosen to produce.

F. Plaintiffs' Requested Relief is Appropriate and Reasonably Tailored.

With their requested relief, Plaintiffs have targeted only those categories of documents likely to be probative of whether Takeda's wrongful listings (and the maintenance and reaffirmation of those listings over time) were the product of a reasonable, good faith belief.²⁷ Plaintiffs have done so to the best of their ability, despite lacking document-specific descriptions and privilege bases in Takeda's logs. Each of the categories of documents Plaintiffs selected is likely to be highly probative of Takeda's beliefs about the scope of the '584 and '404 Patents, its understanding of its listing obligations with respect to those patents between 1999 and 2012, its reasons for falsely listing those patents in 1999 and 2002, and its motives for reaffirming its wrongful listings in 2009 and 2010.

CONCLUSION

Given Takeda's improperly narrow view of its waiver and the many glaring, ongoing issues with its privilege withholdings, Plaintiffs respectfully reiterate their request for an order

²⁷ Plaintiffs do not seek "draft complaints, discovery responses, or settlement agreements in the Actos ANDA litigations," as Takeda claims. (Opp. at 8.) As stated in Plaintiffs' Motion and Proposed Order (ECF Nos. 394, 395) the documents from the underlying patent litigations which Plaintiffs seek are only those relevant to Takeda's defense, including documents regarding Teva's counterclaim challenging Takeda's wrongful listings, and documents concerning Takeda's strategy regarding which infringement claims to bring and maintain against Actos generics.

(1) clarifying that the scope of Takeda's waiver includes all documents relevant to its affirmative defense, including all documents relevant to Takeda's motives for engaging in the alleged misconduct; and (2) compelling Takeda to produce those documents described in Plaintiffs' Motion and Proposed Order (ECF No. 395) by September 23, 2022.

Dated: September 8, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: September 8, 2022

/s/ Thomas M. Sobol
Thomas M. Sobol